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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 09/942,959 | 08/31/2001 | Robert S. Osbakken | 39187-1457 | 7962 |

20985 7590 11/16/2005

FISH & RICHARDSON, PC
P.O. BOX 1022
MINNEAPOLIS, MN 55440-1022

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| EXAMINER |
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JAGOE, DONNA A

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| ART UNIT | PAPER NUMBER |
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1614

DATE MAILED: 11/16/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/942,959

Applicant(s)

OSBAKKEN ET AL.

Examiner

Donna Jagoe

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 12 May 2004.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 67-69,73-85,90-110,112 and 113 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 67-69,73-85,90-110,112 and 113 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 5/12/04, 9/17/04, 1/27/05

- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

Request for Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 12 May 2004 has been entered.

Claims 67-69, 73-85, 90-110, 112 and 113 are pending in this application.

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action:

Claims 67-69, 73-85, 90-110, 112 and 113 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Rubin et al. U.S. Patent No. 5,925,334 (AE) in view of Schmitt et al. U.S. Patent No. 4,950,477 (AA) and Saunders Manual of Medical Practice (U)

The claims are drawn to a method of treating sinusitis comprising nasally administering a pharmaceutical composition comprising betamethasone and a surfactant and optionally a second agent selected from the group consisting of an

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antihistamine, mast cell stabilizer, non-antibiotic anti-microbial agent, an anti-leukotriene, an anti-viral, antiseptic, a non-steroidal anti-inflammatory agent (NSAID), a combination of at least 2 antibiotics, an agent for treating nasal polyps, an anticholinergic agents and combinations thereof.

Rubin et al. teach surfactant such as DPPC and Exosurf ® mixed with an aerosolizing agent to promote mucus clearance (see abstract, see column 4, lines 5-15, see claim 1). The use of the surfactant lowers the surface tension to enhance distribution and spreading of other medications to the lower respiratory tract such as surfactant and an antibiotic and a surfactant and an inhaled anti-inflammatory agent for conditions such as sinusitis (column 10, lines 10-34). Methods of administration of the surfactant composition include a metered dose inhaler, dry powder inhalation, jet nebulization and ultrasonic nebulization (column 9, lines 28-39).

Rubin does not teach particle size, the osmolality, pH or the NaCl equivalency of the composition.

Schmitt et al. teach administration of non-antimicrobial antibiotic such as amphotericin B by aerosol spray to prevent pulmonary infection (column 1, line 60 to column 2, line 4). The particle size of the polyene (amphotericin b) is from 0.5 μm to 8.0 μm . Schmitt et al. teach that the particle size is important because particles smaller than 0.5 μm are exhaled and thus not retained in the lungs while particles greater than 8.0 μm such as those produced in an atomizer do not reach the periphery of the lungs and therefore are not effective in preventing or treating the infection (column 2, lines 48-65).

Schmitt et al. is cited to teach a non-antimicrobial antibiotic and to provide motivation for the instantly claimed particle size. It does not teach treatment of sinusitis and it does not teach osmolality and NaCl equivalency.

Saunders Manual of Medical Practice teach that sinusitis is an inflammation of one or more paranasal sinuses but usually refers to infection of the sinuses (column 1, page 90, 1st paragraph). Further, there may be an overlap between symptoms of acute or chronic sinusitis and other causes of nasal congestion such as allergic or viral rhinitis (column 1, page 90, 4th paragraph). Treatment includes antibiotics such as amoxicillin/clavulanate along with decongestants, mucolytics and other ciliator activators, nasal corticosteroids, antihistamines and saline (pages 91-92).

Saunders Manual is cited to teach the state of the art regarding treatment of sinusitis. It does not teach intra-nasal administration of the agents except the corticosteroids and it does not teach particle size, osmolality and NaCl equivalency of the composition.

It would have been obvious to a person of ordinary skill in the art at the time the invention was made, given the state of the art of the above references to combine the surfactants/antibiotics/anti-inflammatory agents of Rubin et al. with the non-antibiotic antimicrobial agent and particle size of Schmitt et al. and the other agents disclosed in Saunders Manual of Medical practice such as antibiotics, decongestants, mucolytics, nasal corticosteroids and antihistamines to treat sinusitis with the reasonable expectation of preparing formulations with multiple active agents which make the treatment more effective and potent. Furthermore, one of ordinary skill in the art would

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be motivated to optimize the osmotic pressure, pH and NaCl equivalency of the composition, by routine experimentation to include a wider range for different drugs.

Response to Arguments

Applicant asserts that *ACS Hospital Systems, Inc. v. Montefiore Hospital* teach that the combination of the cited references must actually teach or suggest the claimed invention. And that which is within the capabilities of one skilled in the art is not synonymous with that which is obvious. As stated in *In re Kerkhoven*, 626 F.2d 846, 205 USPQ 1069, at page 1072 (CCPA 1980):

It is prima facie obvious to combine two compositions each of which is taught by the prior art to be useful for the same purpose, in order to form a third composition which is to be used for the very same purpose. *In re Susi*, 58 CCPA 1074, 1079-80, 440 F.2d 442, 445, 169 USPQ 423, 426 (1971); *In re Crockett*, 47 CCPA 1018, 1020-21, 279 F.2d 274, 276-77, 126 USPQ 186, 188 (CCPA 1960). As this court explained in *Crockett*, the idea of combining them flows logically from their having been individually taught in the prior art. The fact that a first component is in no way related to the second component, but where each has the same utility, does not detract from the obviousness of combining them. *In re Linder*, 457 F.2d 506, 507 (CCPA 1972). (Holding that it would have been obvious to combine two known dispersants, since one skilled in the art would have expected a mixture of such dispersants to also be a dispersant). Moreover, picking and choosing known components from several references, each which itself discloses a plurality of such components, is permissible where each component has the same

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individual utility. *In re Dial*, 326 F.2d 430 (CCPA 1964). (Holding that it would have been obvious to have combined four individual stabilizers for halogenated hydrocarbon solutions from three different references, where there was no evidence in the record establishing that Applicant's claimed combination of stabilizers was any more effective or in any way otherwise different in inhibiting the decomposition of halogenated hydrocarbons than any single member of that combination. *Id.* at 432.)

In holding an invention obvious in view of a combination of references, there must be some suggestion, motivation or teaching in the prior art that would have led a person of ordinary skill in the art to select the references and combine them in the way that would produce the claimed invention. This motivation may flow from the prior art references themselves, the knowledge of one of ordinary skill in the art, or, in some cases, from the nature of the problem to be solved. Here, filtered through the knowledge of one skilled in the art, Rubin et al. disclosed that clearance of mucus in the respiratory tract can be achieved through inhalation of a surfactant combined with an aerosolizing agent and use of the surfactant lowers the surface tension to enhance distribution and spreading of other medications to the lower respiratory tract such as surfactant and an antibiotic and a surfactant and an inhaled anti-inflammatory agent for conditions such as sinusitis (column 10, lines 10-34). Schmitt et al. teach that the particle size is important because particles smaller than 0.5 μm are exhaled and thus not retained in the lungs while particles greater than 8.0 μm such as those produced in an atomizer do not reach the periphery of the lungs and therefore are not effective in preventing or treating the infection (column 2, lines 48-65). Saunders Manual is cited to

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teach the state of the art regarding treatment of sinusitis. Applicant asserts that the references do not teach chronic sinusitis. It would have been obvious to treat chronic sinusitis with the agents claimed in the manner instantly claimed motivated by the teaching of Rubin et al. that the agents are successful in treating acute sinusitis. Since acute treatment of sinusitis with the agents claimed is successful, one would have been motivated to employ the same agents for the treatment of a chronic sinusitis.

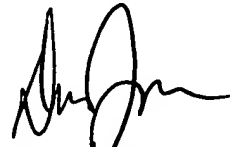
Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Donna Jagoe whose telephone number is (571) 272-0576. The examiner can normally be reached on Monday through Thursday from 9:00 A.M. - 3:00 P.M..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low can be reached on (571) 272-0951. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Donna Jagoe
Patent Examiner
Art Unit 1614

10/14/2005



CHRISTOPHER S. F. LOW
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1800